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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,593	06/30/2003	Marie-Laure Lesaicherre	6565-66285/RJP	5201

7590 06/19/2007

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EXAMINER	
YANG, NELSON C	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
06/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/611,593	LESAICHERRE ET AL.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 2/9/07.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) 17-20 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-16 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 30 June 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ___.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claims 1, 5, 9, and 13 is acknowledged and has been entered.

2. The declaration filed February 9, 2007, is acknowledged and has been entered.

3. Claims 1-20 are pending.

4. Claims 17-20 have been withdrawn.

5. Claims 1-16 are currently under examination.

Rejections Withdrawn

6. The declaration filed on February 9, 2007 under 37 CFR 1.131 is sufficient to overcome the Lesaicherre et al. [Lesaicherre et al., Intein-mediated biotinylation of proteins and its application in a protein microarray, July 2002, J Am Chem Soc, 124, p.8768-8769] reference.

7. Applicant's arguments, see p. 2 and affidavits, filed December 13, 2006 and February 9, 2007, with respect to the rejection of claims 1-16 have been fully considered and are persuasive. The rejection of claims 1-16 under 35 U.S.C. 102(a) and 35 U.S.C. 103(a) has been withdrawn.

Inventorship

8. In view of the papers filed February 9, 2009, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by the deletion of Mahesh Uttamchandani.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 4 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claim 4 recites the limitation "the expression vector" in the last line of the claim. There is insufficient antecedent basis for this limitation in the claim.

12. Claim 11 recites the limitation "the expression vector" in the last line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

14. Claims 1-3, 9, 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Kurz et al. [US 2001/0024789].

With respect to claims 1, 9, Kurz et al. teach nucleic acid-protein fusion entities that contain an N-terminal affinity tag, followed by a suitable intein sequence (para. 0049). After immobilization through the affinity tag, self-cleavage is induced, and the products are released and recovered (see fig. 9, wherein the N-Extein would be the ligand and the C-extein would be the protein) (para. 0049), such as by reaction with a capture molecule that has specificity for and binds a reacted fusion molecule, but not an unreacted fusion molecule (para. 0007). This can be achieved through the use of biotin or specific antibodies that recognize the product structures (para. 0044).

15. With respect to claims 2, 10, Kurz et al. teach that a preferred capture molecule/affinity tag pair is an avidin-biotin pair (para. 0023).

16. With respect to claim 3, Kurz et al. teach supports comprising silicon-glass (para. 0024).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. Claims 4, 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kurz et al. [US 2001/0024789], as applied to claims 1, 9 above, and further in view of Duan [US 6,951,742].

With respect to claims 4, 11, Kurz et al. teach nucleic acid-protein fusion entities that contain an N-terminal affinity tag, followed by a suitable intein sequence (para. 0049). After immobilization through the affinity tag, self-cleavage is induced, and the products are released and recovered (see fig. 9, wherein the N-Extein would be the ligand and the C-extein would be the protein) (para. 0049), such as by reaction with a capture molecule that has specificity for and binds a reacted fusion molecule, but not an unreacted fusion molecule (para. 0007). Kurz et al. fail to teach that the proteins are expressed by a pTYB1 expression vector.

Duan, however, teaches the use of pTYB1 vectors to express fusion proteins, and further teach that pTYB1 vectors allow the cloning of a target gene immediately adjacent to the intein cleavage site, which results in the purification of a native target protein without any vector derived extra residues after the cleavage (column 32, lines 52-65).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use a pTYB1 expression vector to express the fusion proteins of Kurz et al., as suggested by Duan, in order to allow the cloning of a target gene immediately adjacent to the intein cleavage site, allowing for the purification of a native target protein without any vector derived extra residues after the cleavage.

19. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kurz et al. [US 2001/0024789] in view of Duan [US 6,951,742] as applied to claim 4 above and further in view of Xu et al. [US 7,001,745].

With respect to claim 5, Kurz et al. teach nucleic acid-protein fusion entities that contain an N-terminal affinity tag, followed by a suitable intein sequence (para. 0049). After immobilization through the affinity tag, self-cleavage is induced, and the products are released and recovered (see fig. 9, wherein the N-Extein would be the ligand and the C-extein would be the protein) (para. 0049), such as by reaction with a capture molecule that has specificity for and binds a reacted fusion molecule, but not an unreacted fusion molecule (para. 0007). Kurz et al. fail to teach that the ligand is cysteine-biotin and reacting the fusion protein with cysteine-biotin.

Xu et al., however, teach teach a biotinylated peptide possessing an N-terminal cysteine (column 7, lines 11-18), fused to the fusion protein (column 7, lines 10-18), and further teaches that in the presence of MESNA, the efficiency of the ligation is typically greater than 90% (column 7, lines 20-22).

Therefore, one of ordinary skill in the art at the time of the invention would have been motivated to have used biotinylated peptides possessing an N-terminal cysteine in the method of Kurz et al. and Duan, as suggested by Xu et al., in order to increase the efficiency of ligation.

20. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kurz et al. [US 2001/0024789] in view of Duan [US 6,951,742] and Xu et al. [US 7,001,745], as applied to claim 5 above, and further in view of Bradley et al. [US 2002/0006623].

With respect to claims 6, 7, Kurz et al. teach nucleic acid-protein fusion entities that contain an N-terminal affinity tag, followed by a suitable intein sequence (para. 0049). After immobilization through the affinity tag, self-cleavage is induced, and the products are released and recovered (see fig. 9, wherein the N-Extein would be the ligand and the C-extein would be the protein) (para. 0049), such as by reaction with a capture molecule that has specificity for and binds a reacted fusion molecule, but not an unreacted fusion molecule (para. 0007). Kurz et al. fail to teach that the glass support is derivatized with an epoxy silane compound such as glycidoxypropyl trimethoxysilane.

Bradley et al., however, teach the dervizatization of glass supports with glycidoxypropyl trimethoxysilane (para. 0127), and further teach that glycidoxypropyl trimethoxysilane is rapid, and occurs under very mild conditions using a minimum of inexpensive reagents (para. 0128).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have derivatized the glass supports of Kurz et al. with glycidoxypropyl trimethoxysilane, as suggested by Bradley et al., in order to be able to attach ligands to the glass support rapidly, and under very mild conditions while using a minimum of inexpensive reagents, which would render it cheaper, quicker, and simpler that other methods.

21. With respect to claim 8, Kurz et al. teach streptavidin (para. 0023).

22. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kurz et al. [US 2001/0024789] in view of Duan [US 6,951,742] as applied to claim 11 above, and further in view of Inoue et al. [US 2002/0123101].

With respect to claim 12, Kurz et al. teach nucleic acid-protein fusion entities that contain an N-terminal affinity tag, followed by a suitable intein sequence (para. 0049). After immobilization through the affinity tag, self-cleavage is induced, and the products are released and recovered (see fig. 9, wherein the N-Extein would be the ligand and the C-extein would be the protein) (para. 0049), such as by reaction with a capture molecule that has specificity for and binds a reacted fusion molecule, but not an unreacted fusion molecule (para. 0007). Kurz et al. fail to teach that or that the fusion protein is contacted with a chitin column.

Inoue et al., however, teach that chitin column are commonly used for purification of proteins. (para. 0217).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention for Kurz et al. and Duan to have the fusion proteins come in contact with a chitin column, in order to purify the protein, as suggested by Inoue et al., so that there would be no contaminants that would potentially interfere and contaminate the protein array, thus allowing for better quality in the protein arrays produced.

23. Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kurz et al. [US 2001/0024789] in view of Duan [US 6,951,742] and Inoue et al. [US 2002/02123101], as applied to claim 12 above, and further in view of Xu et al. [US 7,001,745].

With respect to claim 13, Kurz et al. teach nucleic acid-protein fusion entities that contain an N-terminal affinity tag, followed by a suitable intein sequence (para. 0049). After immobilization through the affinity tag, self-cleavage is induced, and the products are released and recovered (see fig. 9, wherein the N-Extein would be the ligand and the C-extein would be

the protein) (para. 0049), such as by reaction with a capture molecule that has specificity for and binds a reacted fusion molecule, but not an unreacted fusion molecule (para. 0007). Kurz et al. fail to teach that the ligand is cysteine-biotin, and the step of attaching the ligand comprises adding cysteine biotin to a chitin column.

Xu et al., however, teach teach a biotinylated peptide possessing an N-terminal cysteine (column 7, lines 11-18), fused to the fusion protein (column 7, lines 10-18), and further teaches that in the presence of MESNA, the efficiency of the ligation is typically greater than 90% (column 7, lines 20-22).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used biotinylated peptides possessing an N-terminal cysteine in the method of Kurz et al. and Duan, as suggested by Xu et al., in order to increase the efficiency of ligation.

24. With respect to claim 14, Kurz et al. teach supports comprising silicon-glass (para. 0024).

25. With respect to claim 15, Kurz et al. teach streptavidin (para. 0023).

26. With respect to claim 16, Duan teaches spotting the protein onto a solid surface to form an array (column 37, lines 1-25).

Response to Arguments

27. Applicant's arguments with respect to claims 1-16 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

28. No claims are allowed.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

31. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nelson Yang
Patent Examiner
Art Unit 1641